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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,452	06/14/2006	Andreas Lendlein	26538-0016	3000

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WASHINGTON, DC 20004

EXAMINER

MCEVOY, THOMAS M

ART UNIT	PAPER NUMBER
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3731

NOTIFICATION DATE	DELIVERY MODE
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09/02/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

dcptopatent@hhlaw.com
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Office Action Summary	Application No. 10/560,452	Applicant(s) LENDLEIN ET AL.	
	Examiner THOMAS MCEVOY	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 16-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4 and 16-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/25/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 17th 2009 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3, 4, 16, 17, 31-34, 37, 39, and 41-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phan et al. (US 5,603,722) in view of Langer et al. (US 6,388,043).

Phan et al. disclose the invention as claimed including a stent (ref. 10) made from one non-metallic SMP (col. 4, lines 44-47; col. 5, lines 56-col. 6, line 12), the stent having at least one stimuli-triggered shape in memory (col. 4, lines 55-59). Phan et al. suggest providing memory shapes for the expanded and the contracted states (col. 5, lines 1-8) but fail to disclose two stimulus-triggered shapes in memory. Langer et al.

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disclose shape memory polymers which have two stimulus-triggered memory shapes; expanded and contracted (Figure 2 and elsewhere), where Applicant has disclosed that the SMP's of Langer et al. are suitable for their invention. It would have been obvious to one of ordinary skill in the art to have used the SMP's of Langer et al. with the stent of Phan et al. in order to provide the stent with memory shapes for the expanded and contracted states. Phan et al. further disclose the SMP material being a thermoplastic, the stimuli being a thermal change or a pH change, and a method of placing the stent in a vessel (col. 7, lines 20 - col. 8, line 3) including placing the stent on a balloon catheter, inserting the stent, expanding the stent, and fixing the stent. Many of the ingredients used to construct the SMP's of Pham et al. or Langer et al. have no shape memory in their purified state until combined and formulated to become part of an SMP. Regarding claims 18-27, Phan et al. discloses the invention substantially as claimed except for the e-module of the SMP material, the reset fixation value of the SMP material, or the reset ratio of the SMP material. Langer et al. teach that it is desirable to provide SMP's for stents with the claimed properties at or near the claimed values (col. 6, lines 45-52; Table 13; Table 15 and elsewhere). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used an SMP material with the above limitations and the ranges as recited in the claims since at least some are directly taught by Langer et al. desirable for SMP's and furthermore, since it has been held that where the general conditions of a claim (as shown in Tables 13, 15 and elsewhere) are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Furthermore, Applicant has not

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disclosed that the claimed values and ranges solve any stated problem, produce any unexpected results or are for any particular purpose other than the same purpose which the other SMP's in Applicant's disclosure serve (unless Applicant is stating that all the disclosed SMP's possess these properties in the claimed amounts). It appears that the invention would perform equally well if possessing the claimed properties in amounts outside the claimed values and ranges. Applicant has disclosed that any SMP is suitable for use with their invention (paragraph 0113 of Applicant's pre-grant publication) and has not disclosed how or why the specific materials with the claimed values and ranges would perform better for the intended use. Applicant has also disclosed that all the polymer networks of their invention (including those disclosed as known in the prior art) have greater than 90% reset fixation values (paragraph 0147 of Applicant's pre-grant publication). Therefore, it would have been an obvious matter of design choice to use SMP's with these values and ranges in constructing the stent of Pham et al.

Regarding claims 28, 29, 38, and 40, Phan et al. disclose that the SMP can comprise a caprolactone unit, a cross-linked caprolactone macromonomer (cross-linked polycaprolactone) and/or a claimed therapeutic agent. (col. 5, lines 25-30 and 56-67).

Regarding claim 30, the stent can be extruded (col. 5, line 45 and elsewhere).

Regarding claims 35 and 36, Phan et al. disclose the invention substantially as claimed except for removing the stent of claim 1. It is old and well known in the art to remove stents from the body for a variety of medical reasons. Evidentiary support can be provided upon Applicant's request. It would therefore have been obvious to one of ordinary skill in the art to remove the stent of Pham et al. for a variety of medical

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reasons. Pham et al. suggest providing stimulus-triggered, memorized contracted states. It would have been obvious to one of ordinary skill in the art to have used the same methods in forming the stent to reduce the size of the stent in the vessel in order for it to be removed; for instance using a different temperature. Since the stent can be delivered by using one of the recited stimuli, it would be obvious to use the same stimuli, but in reverse, to remove the stent. Furthermore, as modified by Langer et al., this modification would be possible since the SMP would have two memory shapes as described above.

Response to Arguments

3. Applicant's arguments with respect to the pending claims have been considered but are moot or addressed above in view of the modified ground(s) of rejection.

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas McEvoy whose telephone number is (571) 270-5034. The examiner can normally be reached on M-F, 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

5. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas Mcevoy/
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
8/28/09